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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,855	10/13/2000	Chaitan Khosla	286002021100	6952

25225 7590 09/26/2003
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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,855

Applicant(s)

KHOSLA ET AL.

Examiner

Kathleen M Kerr

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,53-56 and 58-77 is/are pending in the application.
- 4a) Of the above claim(s) 75-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,53-56 and 58-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: LIGAND attachment.

DETAILED ACTION

Application Status

1. In response to the previous Office action on the merits, a Final rejection (Paper No. 14, mailed on November 25, 2003), Applicants filed an after-final amendment and response received on April 29, 2003 (Paper No. 16). Said amendment was entered upon the RCE filed on July 21, 2003 (Paper No. 20) and cancelled Claim 57 and amended Claims 55, 58-63, 66, and 69-71. Thus, Claims 1, 53-56, and 58-77 are pending in the instant Office action. Claims 75-77 remain withdrawn from consideration as non-elected inventions. Claims 1, 53-56, and 58-74 will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/159,090 filed on October 13, 1999, 60/206,082 filed on May 18, 2000 and 60/232,379 filed on September 14, 2000.

Withdrawn - Objections to the Specification

3. Previous objection to the title is withdrawn by virtue of Applicants' amendment.

Withdrawn - Claim Objections

4. Previous objection to Claims 58 and 66 for typographical errors is withdrawn by virtue of Applicants' amendment.

Withdrawn Claim Rejections - 35 U.S.C. § 112

5. Previous rejection of Claim 55 under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of the phrase “the expression system for biotin ligase” is withdrawn by virtue of Applicants’ amendment.
6. Previous rejection of Claim 57 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “has no functional endogenous pathway for propionate catabolism” is withdrawn by virtue of Applicants’ cancellation of said claim.
7. Previous rejection of Claims 59, 60, 67, 68, 73, and 74 under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviations “DEBS” and “6-dEB” is withdrawn by virtue of Applicants’ amendment.
8. Previous rejection of Claims 1, 53, 56-60 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for host cells expressing functional propionyl CoA carboxylase as a result of co-expressing biotin ligase, does not reasonably provide enablement for host cells expressing propionyl CoA carboxylase in the absence of co-expressing biotin ligase is withdrawn by virtue of Applicants’ arguments that *E. coli* already express biotin ligase necessary for the production of active propionyl-CoA carboxylase. While Rodriguez *et al.* (see specification, page 6) describe the addition of birA (via an expression system) to enhance the activity of the overexpressed propionyl CoA carboxylase, it is active in an *E. coli* expression system in the absence of the added birA. Moreover, the claims are drawn to host cells that only must synthesize a polyketide and must have an expression system to

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produce an active propionyl CoA carboxylase. By virtue of the specification and the art, it is clear that host cells without exogenously added biotin ligase will not *efficiently* produce either, but *efficient* production is not a requirement of the claims.

9. Previous rejection of Claim 57 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' cancellation of said claim.

Maintained - Claim Rejections - 35 U.S.C. § 112

10. Previous rejection of Claims 61, 64-69, and 72-74 under 35 U.S.C. § 112, first paragraph, new matter, and under 35 U.S.C. § 132 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that support for using *Streptomyces* host cells genetically modified to contain at least an *matB* gene from *S. coelicolor* or *R. trifoli* is found on page 6, lines 3-4 and on page 7, lines 2-7; the Examiner disagrees with this interpretation of the disclosure. The excerpt on page 6 is as follows:

“In one embodiment of this aspect, advantage is taken of the *matABC* operon, which was recently cloned from *Rhizobium trifoli* (An, J.H., et al., Eur. J. Biochem. (1988) 15:395-402). There are three proteins encoded by this operon.

MatA encodes a malonyl-CoA decarboxylase, which normally catalyzes the reaction: malonyl-CoA --> acetyl-CoA + CO₂.

MatB encodes a malonyl-CoA synthetase which catalyzes the reaction: malonic acid + CoASH --> malonyl-CoA (in an ATP dependent reaction).

MatC encodes a malonate transporter which is believed to be responsible for transport of malonic acid across the cell membrane.” (pages 5-6, bridging paragraph)

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This embodiment describes using the entire operon, not any one gene of the operon. The excerpt on page 7 is as follows:

“Purified MatB is particularly advantageously used for the preparative cell free production of polyketides, since CoA thioesters are the most expensive components in such cell-free synthesis systems. Alternatively, as set forth above, these genes are used (in any suitable combination) in a general strategy for production by cells in culture of these substrates. MatB and MatC can be used to effect production of any alpha-carboxylated CoA thioester where the corresponding free acid can be recognized as a substrate by MatB.” (page 7)

This embodiment first describes using purified MatB protein, which is not related to the instant claims to a genetically modified *Streptomyces* host cell. Second, this embodiment describes using the genes, presumably the genes *matABC*, in any suitable combination and then describes using *matBC* together. Thus, nowhere is the solitary use of a *matB* gene taught by the specification as originally filed.

Additionally, the Examiner notes that Claim 61 contains many more specifics (particular host cell genus and particular *matB* genes) that are absent from the embodiments described by Applicants as supporting the scope of the claims.

11. Previous rejection of Claims 1 and 53-56, and 58-74 are rejected under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that the specification not only describes *pccB* and *accA2* from *S. coelicolor* but also “their homologs in other organisms” as provided by the art, such as Samols *et al.* (JBC (1988) 263:6461-6464) provided with Applicants' response. As noted by Applicants, Samols *et al.* describe biotin-dependent carboxylases in general and specifically, only rat and

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human in Figure 4 (page 6463). Samols *et al.* generalizes over all biotin enzymes and not just the subgenus claimed herein. Thus, the Examiner fails to see how this reference supports written description of the claimed invention. However, because propionyl CoA carboxylase is a known enzyme with a known function (see E.C. 4.1.4.41) and conserved structure as evidenced by the numerous examples of the known enzyme, the name propionyl CoA carboxylase would be sufficient written description for the claimed genus.

However, the Examiner will add the following issue to the previously set forth rejection. The claimed host cells require a propionyl CoA carboxylase with a particular activity - that synthesizes 2S-methylmalonyl CoA. The specification tests to identify that pccB and accA2 from *S. coelicolor* in fact have this function. It is unclear from the art if **all** propionyl CoA carboxylases (E.C. 4.1.4.41) have this function, that is are particular for the 2S racemer, which specificity is crucial to the claimed invention as noted throughout the instant specification. The specification provides no structural reason why pccB and accA2 from *S. coelicolor* have this function to help describe this subgenus of all propionyl CoA carboxylases (E.C. 4.1.4.41). Thus, the instant rejection is maintained for Claims 1, 56, and 58-60 for this issue.

Applicants argue that the specification has adequate written description for the expression system of phosphopantetheinyl transferases due to the reference to 08/728,742 now USPN 6,579,695. Firstly, the Examiner notes that a rejection under 35 U.S.C. § 112, second paragraph, is newly set forth below since this enzyme seems to only be defined by this USPN. Assuming as broadly as possible, that the term phosphopantetheinyl transferases reads on any enzyme having the ability to phosphopantetheinylate a substrate *in vitro* and has some structural similarity to the homologs described in USPN 6,579,695, the claimed invention would not synthesize a

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polyketide since not all phosphopantetheinylating enzymes function to phosphopantetheinylate PKSs as evidenced by the fact the *E. coli* o195 protein has little phosphopantetheinylation activity and *E. coli* ACPS has none as shown in USPN 6,579,695 and USPN 6,258,566, respectively. Thus, the claims must be limited to phosphopantetheinylating enzymes that phosphopantetheinylate PKSs. The specification does not describe, except by function, this subgenus of phosphopantetheinylating enzymes since no structural reasons are presented in either the instant application or USPN 6,579,695 so that one of skill in the art could recognize the subgenus claimed. Thus, the instant rejection is maintained for Claims 1, 53-55, 58-60, and 69-74 for this issue.

Applicants argue, “a skilled artisan would understand that the applicants had possession of the genus of biotin ligases and not merely the species of birA from *E. coli*....” The Examiner notes that it is not the skilled artisan’s “understanding” but what is adequately described in the specification that is of issue here. Firstly, the Examiner notes that a rejection under 35 U.S.C. § 112, second paragraph, is newly set forth below since this enzyme seems to only be defined by the term “biotin ligase” which is not an enzyme classification category. Thus, every biotin ligase category noted in the art (E.C. 6.2.1.11, 6.3.4.9, 6.3.4.10, 6.3.4.11, and 6.3.4.15). The articles cited by Applicants describe biotin enzymes in general and birA counterparts, but the claims are limited to neither of these. Thus, the skilled artisan would be unable to identify the subgenus of biotin ligases that are presumably under E.C. 6.3.4.15 and intended in the claim from the genus of all biotin ligases by means of structure or function. Thus, the instant rejection is maintained for Claim 54 for this issue.

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Lastly, Applicants argue that the amendment to Claims 61-74 obviate the instant rejection with respect to the *matABC* genes; this is not the case based on particular claim language. In Claim 61, the genus is to any *matB* from *S. coelicolor* or *R. trifoli* and not those specifically described in the specification (as from An, 1998 and GenBank Accession Number AL163003). Claim 61 would need to read ---incorporation of the *matB* gene from *S. coelicolor* or the *matB* gene from *R. trifoli*---. This same remedy can be sought for Claims 62-63 and 69-71; for Claims 66, 71 and 72, the wherein phrase should be ---where the *matB* gene is the *matB* gene from *R. trifoli*--- (the Examiner notes that Claim 66 was not previously considered at issue here, but the Examiner's reasoning has been amended to include said claim). Thus, the instant rejection is maintained for Claims 61-74 for this issue.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

12. Previous rejection of Claim 63 under 35 U.S.C. § 102(b) as being anticipated by Kao *et al.* is withdrawn by virtue of Applicants' amendment requiring *matA* be from *R. trifoli*, which is not taught by Kao *et al.*

Maintained - Claim Rejections - 35 U.S.C. § 102

13. Previous rejection of Claims 61, 62, 64, 65 and 67-68 under 35 U.S.C. § 102(b) as being anticipated by Kao *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that the term "added *matB* gene" distinguishes Claim 61 from *S. coelicolor* that naturally have *matB* copies; this is not the case. Applicants are interpreting the claimed product to require some particular process to make it; however, the same product made by another process still reads on the claim. There is

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nothing in the limitations of Claim 61 that preclude the incorporation of “added” matB via homologous recombination at the same site in native *S. coelicolor* thus producing a product that looks just like that which has had matB “added”. Nowhere in the claims are additional copies of matB required.

NEW ISSUES

Objections to the Specification

14. The specification is objected to for citing outdated U.S. patent application numbers

- a) On page 5, line 14, U.S. Application 08/728,742 is now U.S.P.N. 6,579,695;
- b) On page 11, line 5, U.S. Application 0/311,756 is now U.S.P.N. 6,500,960; and
- c) On page 12, line 17, U.S. Application 0/073,538 is now U.S.P.N. 6,558,942.

Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1, 53-55, 58-60, and 69-73 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “phosphopantetheinyl transferase” is unclear. The specification uses a specific example of a phosphopantetheinyl transferase in the form of the *sfp* gene from *B. subtilis* in Example 4. The specification further describes phosphopantetheinyl transferases as the genes disclosed in 09/728,742 (USPN 6,579,695). In this patent, numerous

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ACP synthase (phosphopantetheinyl transferase) homologs are listed in Table IV (column 30), but few are functionally tested (sfp, EntD, and o195 with 0195 having limited activity as shown in Figure 11). The Examiner notes that *E. coli* expression of active PKS systems has not been shown without additional incorporation of sfp (*B. subtilis*), EntD (*E. coli*), or Gsp (*B. brevis*) (see USPN 6,258,566) despite the endogenous presence of homologs like o195 natively in *E. coli*. The art provides no enzyme classification for phosphopantetheinyl transferases that one of skill in the art could use as a generic definition. Thus, the metes and bounds as based solely on the referenced US Patent are unclear. Clarification is required.

16. Claim 54 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “biotin ligase” is unclear. In the art, no less than five enzyme classifications are considered biotin ligases (see attachment from LIGAND). Only one of these, E.C. 6.3.4.15, is encoded by a birA gene as specifically described in Example 4 of the instant specification. Thus, it is unclear if any biotin ligase is within the scope of the claim or if only E.C. 6.3.4.15 enzymes are within the scope of the claim. Clarification is required.

17. Claim 58 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “disabled” is unclear as to its metes and bounds. To disable an operon implies prohibiting gene expression, but this limitation is not actually in the claim. Must the prpA-D be deleted? Must the prpA-D merely not be expressed? Must active prpA-D not be expressed? Clarification and/or amendment are required.

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18. Claim 66 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “the mat gene” has improper antecedent basis since in Claim 61, only a matB gene is referred to. The Examiner suggests deleting “the mat gene” and substituting therefor ---the added matB gene--- for clarity.

19. Claim 67 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “the PKS” has no antecedent basis in Claim 61. Clarification is required.

20. Claim 72 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “the mat gene” has improper antecedent basis since in Claim 69, only a matB gene is referred to. The Examiner suggests deleting “the mat gene” and substituting therefor ---the matB gene--- for clarity.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claim 58 is rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for host cells whose prpA-D operon is deleted or not

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expressed (via endogenous promoter deletion), does not reasonably provide enablement for host cells whose *prpA-D* operon expresses inactive enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To produce such cells by means other than deleting the *prpA-D* operon or its endogenous promoter would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

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The instant specification describes so as to enable a single example of host cells whose endogenous propionate catabolic pathway is disabled by deletion of the prpA-D operon. The art enabled identification of an endogenous promoter or promoters that control expression of the prpA-D operon, which promoters could be deleted within the skill of the art so that the prpA-D genes are not expressed. The specification provides no guidance as to how to produce inactive prpA-D gene products, in particular by replacing the prpA-D genes with genes encoding inactive gene products. The art is such that inactivation of enzymes by means other than deletion is wholly unpredictable. Thus, the instant claim is not enabled to the full extent of its scope.

Summary of Pending Issues

22. The following is a summary of the issues pending in the instant application:

- a) The specification stands objected to for citing outdated U.S. patent application numbers.
- b) Claims 1, 53-55, 58-60, and 69-73 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “phosphopantetheinyl transferase”.
- c) Claim 54 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “biotin ligase”.
- d) Claim 58 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “disabled”.
- e) Claims 66 and 72 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for improper antecedent basis of “the mat gene”.
- f) Claim 67 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “the PKS” having no antecedent basis.
- g) Claims 61, 64-69, and 72-74 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
- h) Claims 1 and 53-56, and 58-74 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- i) Claim 58 stands rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
- j) Claims 61, 62, 64, 65 and 67-68 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kao *et al.*

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Allowable Subject Matter

23. The following is reiterated from the previous Office action:

“The Examiner notes that the concept of precursor feeding in heterologous polyketide systems is not a novel one. In particular, Stassi *et al.* teach that the heterologous expression of a recombinant modular PKS requires the addition of butyryl-CoA, in the form of media supplementation or by means of co-expression of recombinant crotonyl-CoA reductase for the production of butyryl-CoA. While the propionyl CoA carboxylase and malonyl biosynthesis expression systems are recognized as producing PKS precursors (see Rodriguez *et al.*, Hyang *et al.* and GenBank Accession Number AL163003), no direct link between expression systems for these particular precursors and expression systems for modular PKSs is established in the art. Moreover, expression of phosphopantetheinyl transferases such as *sfp* are well known to be required for effective heterologous expression of PKS systems in *E. coli* (see Barr *et al.* in WO98/27203). But again, no direct link between *sfp* expression and propionyl CoA carboxylase or malonyl biosynthesis expression systems is taught or indicated in the prior art.”

Conclusion

24. Claims 1 and 53-56, and 58-74 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



KMK

September 23, 2003